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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**MDL No. 2327**
	2:12-md-02327
THIS DOCUMENT RELATES TO:	**HON. JOSEPH R. GOODWIN**
Darla G. Ray, et al. v. Ethicon, Inc.., et al No. 2:12-cv-04475	

RULE 26 EXPERT REPORT OF KONSTANTIN WALMSLEY, MD

My name is Konstantin Walmsley. I have been retained by the Motley Rice Law Firm to give medical opinions related to Darla Ray. I am being compensated at the rate of $500 dollars/hour. My curriculum vitae and schedule of previous testimony are attached to this report. All opinions set forth in this report are based upon my personal knowledge, as well as my review of the pertinent medical records, my education, training, skill, experience as a physician, and review of the pertinent medical literature. All of my opinions are based upon a reasonable degree of medical probability.

I am a licensed physician in the State of New Jersey and a board certified urologist. I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh and am familiar with the properties of these devices and proper implantation technique for these devices.

I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh, including mid urethral slings, and am familiar with the properties of these devices and proper implantation technique for these devices. Further, I am familiar with non-mesh options for the treatment of stress urinary incontinence including the pubovaginal sling. I have attending training

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provided by Ethicon, Inc. regarding the TVT-O device. I have explanted and performed other revision procedures on transobturator and retropubic mid-urethral slings including the TVT-O device.

Additionally, in light of my training, knowledge, experience and qualifications as set forth above and in the attached C.V., I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants.

The most common complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion, exposure or protrusion of mesh into and through tissues or organs, voiding dysfunction relating to pelvic floor scarring (de novo urinary urgency, urge incontinence, and incomplete emptying), and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the cause of the patients complications based upon an interview with the patient, a review of her medical records, and knowledge of her prior medical history.

I have reviewed the following medical records

- North Mississippi Medical Center-West Point;
- William Billington, DO;
- The Womens Group-West Point;
- Family Medical Care;
- Neurosurgical Services-North Mississippi Medical Center;
- Trace Family Health Clinic
- Pearson Drug Company
- The Women's Group-Columbus

In addition to the review of the medical records listed above, I performed an independent medical examination of Ms. Ray on January 12th, 2017. I have also reviewed the following medical literature and other TVM related documents (provided as my reliance list in Appendix 1) and have relied, in part, on these documents in addition to my medical and clinical experience in forming my opinions:

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Clinical History

- On May 4th, 2009, Ms. Ray presented to Dr. Pete Wisniewski with complaints of depression, anxiety, neck pain and pain in her left ovary. Her past medical history was in part remarkable for chronic neck and back pain as well as hypertension. She was a known active smoker. Her obstetrical history was remarkable for 4 pregnancies and 2 vaginal deliveries with the patient having had 2 abortions.

- On July 30th, 2009, Ms. Ray complained about overactive bladder (OAB) symptoms to Dr. Wisniewski. She was prescribed an anticholinergic medicine.

- On August 25th, 2009, she noted significant improvement with her OAB symptoms.

- On October 9th, 2009, Dr. Wisniewski noted that her incontinence had improved but not been cured with medication, although she now had a dry mouth.

- On August 23, 2010, Ms. Ray presented to the Emergency Room with "significant pain and discomfort. Lower abdomen tenderness and bladder pain and discomfort." The physical exam noted she was "grossly tender in the suprapubic area" and urinalysis was "obviously infected." She complained of urgency, frequency and pain on urination. The assessment included dysuria and frequency. She was treated with Cipro and antispasmodics and instructed to sit in a hot tub of water. The notes also stated "Go see Dr. Shields in West Point regarding her bladder dysfunction for fear that she may need an AP repair. Follow up with her then."

- She reported at least two other possible UTI's and possible kidney stones to her family physician in 2008 and 2009.

- On August 30, 2010, Ms. Ray was referred to the Women's Group-Columbus by Dr. Shields for urodynamics. She complained of nocturia and urine loss with Valsalva. After performing the study, Dr. Charles Miles determined she had urethral hypermobility.

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- On October 25th, 2010, Ms. Ray underwent placement of a TVT-O tape by Dr. Shields. The sling was placed in a tension-free fashion and Dr. Shields performed cystoscopy to confirm no injury to the lower urinary tract.

- On September 25, 2012, Ms. Ray reported to Trace Family Health Clinic that she had urinary urgency, dribbling after urination and occasional incontinence. Since her mesh implant, she has reported multiple UTI's and occasional blood in her urine.

Methodology

My general opinions based upon my clinical experience and review of medical and scientific literature and well as my medical education, knowledge, training, practice, and clinical experience.

My case specific opinions are based upon a differential diagnosis methodology. In determining the specific cause of an injury in the medical context it is necessary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause.

General Opinion No. 1

Facilitating informed consent is an integral part of the practice of medicine. I agree with AMA 8.08 on informed consent. The patient's right of self-decision is particularly important when surgical intervention regarding a permanent medical device is being considered by the patient.

Before a surgeon can inform a patient on the risks/benefits/alternatives to any procedure, including the TVT-O, the surgeon must be informed on the risks/benefits/alternatives. I have read and relied on Instructions for Use (IFU) for medical devices when informing myself on the risks/benefits/alternatives to a given procedures – including mid-urethral slings. I incorporate the risks and complications referenced in the IFU into my risk benefit conversation with the patient. I expect the risk and complication information as presented in the IFU to be accurate.

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It is my opinion the IFU for the TVT-O in 2010 was not sufficient to enable informed consent from the patient. The TVT-O IFU provided:

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination.
- Over correction i.e. too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

The words "transitory" and "transient" carry a specific medical meaning. Mosby's medical dictionary defines transient as "pertaining to a condition that is temporary." Using the word transient to describe the human body's foreign body response to the TVT-O mesh implies the response dissipates with time. In my experience, this does not accurately describe the human body's foreign body response to transvaginal placed mesh.

In my experience when dealing with synthetic mesh-induced foreign body response, the degree of inflammation and scarring around the mesh is intense and

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chronic. More often than not, when removing exposed mesh, I am unable to completely remove the entire mesh implant because of the intensity of inflammation and extensive scarring induced by mesh incorporation into the host tissues. Moreover, in all of my experiences removing mesh, residual scarring of the vagina and peri-vaginal tissues persists and is even more severe in the instances where residual pelvic mesh is left in the patient.

The TVT-O IFU does not mention: mesh contraction; dyspareunia; mesh shrinkage; scar plate formation; or the difficulty in removing mesh in the event of an adverse event. These events are all part of my informed consent conversation today. I have treated patients implanted with mid-urethral slings, including the TVT-O for these conditions. These events were reported in the mid-urethral sling literature prior to when Ms. Ray was implanted. In my opinion, a patient considering a mid-urethral sling cannot be properly consented without discussing these potential adverse events.

General Opinion No. 2

Safer alternatives designs and procedures existed in 2010 that have a lesser risk of erosion and dyspareunia with substantially equivalent efficacy.

In 2010, alternative successful and safer sling procedures were available, including biologic slings or autologous fascial slings using rectus fascia sutured to the bladder neck and tied to itself over the rectus fascia. Ms. Ray was unable to receive proper informed consent relating to such safer alternatives because of the lack of information in the TVT-O IFU inherent to the risks of using synthetic mesh as an alternative to autologous fascia. As such, Dr. Shields was unable to warn Ms. Ray of the subsequent complications she has suffered from.

Case Specific Opinion No. 1

Ms. Ray suffered scar plate formation as a result of the physical properties of the TVT-O device. These conditions are documented in my IME.

A. Scar Plate

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During my physical exam of Ms. Ray, I palpated mildly indurated tissue in the area of her sling.

I have observed scar plate formation in patients such as Ms. Ray who have had a TVT-O slings implanted.

Case Specific Opinion No. 2

Mrs. Ray's dyspareunia was caused in part by scar plate formation related to her TVT-O. Recognized causes of dyspareunia following synthetic sling surgery include: (1) erosion/extrusion; (2) mesh contraction; (3) paraurethral banding; (4) scarring with reduced elasticity; (5) infection and inflammation including but not limited to vestibulitis; (6) neuromuscular injury (7) lichen sclerosis; (8) vaginal tissue atrophy; and (9) pelvic floor dysfunction.

I am able to rule in scarring with reduced elasticity as a potential cause of Ms. Ray's dyspareunia. This condition was identified during my IME of Ms. Ray.

I am able to exclude paraurethral banding, mesh erosion, and mesh contraction as causes of Ms. Ray's dyspareunia because I have seen not identified these findings either in the medical records or during my IME.

I am able to exclude vestibulitis, lichen sclerosis, neuromuscular injury, and pelvic floor dysfunction as causes of Ms. Ray's vaginal pain as these conditions have never been diagnosed or identified as part of Ms. Ray's medical history

Vaginal tissue atrophy is a possible contributing cause of Ms. Ray's dyspareunia as she was peri-menopausal at the time of her sling surgery and had findings of atrophic vaginitis during my IME.

Case Specific Opinion No. 3

Ms. Ray continues to have dyspareunia and voiding dysfunction presently. As part of my expert review and preparation of my opinion regarding Ms. Ray, I performed an independent medical exam of this patient on January 12th, 2017. At that time, the patient reported several bothersome symptoms including voiding

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dysfunction and dyspareunia. Her voiding dysfunction consisted of urinary incontinence, primarily urgency urinary incontinence, using 3-4 thick pads/day that were wet when changed, significantly worse than the one pad per day she was using prior to sling surgery. She also described having symptoms consistent with recurrent UTIs. She described having dyspareunia about six months following her sling surgery describing a "hard spot" being "hit" during intercourse.

Additional significant findings include mildly indurated tissue in the area of her sling without identifiable tenderness on exam. As part of the foreign body reaction to synthetic mesh the periurethral, perivesical, and vaginal tissues create dense fibrotic scar tissue which compromises the elasticity and compliance of these tissues. As such, when patients present with complications from synthetic mesh slings, they tend to develop a combination of voiding dysfunction, sometimes manifest as obstructive in nature, in addition to urinary incontinence that is often both stress incontinence in combination with urgency urinary incontinence. This relates to a combination of factors, one being the development of non-compliant "pipestem" urethral tissues that are unable to coapt and therefore hold urine; the second factor relates to a combination of (1) inflammation rendering the bladder muscle (or detrusor muscle) unstable, as well as (2) scarring of the bladder muscle adjacent to the synthetic mesh foreign body response, in which the bladder muscle's ability to contract is compromised because of scarring and fibrosis.

Case Specific Opinion No. 4

Ms. Ray's future prognosis as it relates to her dyspareunia and voiding dysfunction is guarded. Because she has pelvic mesh still inside of her body, she will continue to suffer from dyspareunia. Even if she were to have all of her mesh removed, the surgery require to execute this procedure is extensive, complicated, and almost exclusively performed in tertiary academic centers. I anticipate that if heroic surgery were performed to remove all of her mesh that she would develop further scarring and fibrosis inherent to this procedure.

In as much an autologous fascial sling or other procedures (not involving synthetic mesh) for incontinence might be considered if her mesh were to be removed, these would be inappropriate at the current time because of the fact that she still has a mesh sling present. Autologous fascial slings placed in the setting of scar tissue, a likely finding should she have her sling removed, would have a lower success rate and a higher complication rate than if it were performed in the absence

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of scarring. For this reason, Ms. Ray is not a candidate for this type of surgery and is best treated with medical therapy in combination with lifestyle modifications and pelvic floor physiotherapy. Although these interventions should be somewhat helpful, they most certainly will not completely resolve the voiding dysfunction she currently suffers from.

With regards to her dyspareunia, her symptoms might be ameliorated with sling removal in combination with transvaginal Estrogen cream therapy. Once again, the surgical removal of her mesh would be a heroic procedure performed in a tertiary academic center and would likely create further fibrosis and scarring which would more likely than not result in persistent dyspareunia. In summary, within a reasonable degree of medical certainty, the voiding dysfunction, and dyspareunia will be a lifelong condition for this patient. Moreover, alternative successful and safer sling procedures were available at the time of her original synthetic mesh sling implantation, including the use of a biologic or autologous graft with suture. These safer alternative sling procedures would not have resulted in the same symptoms and injuries that Ms. Ray now suffers.

These represent my current opinions in this case. As any additional material becomes available, I reserve the right to modify or add to this opinion.

Sincerely,

Konstantin Walmsley, M.D.

Progress Note

Patient Name:	Darla Ray	**Visit Date:**	January 12, 2017
Patient ID:	858631	**Provider:**	Konstantin Walmsley, MD
Sex:	Female	**Location:**	NJU-P24 (Glen Ridge)
Birthdate:	December 31, 1958	**Location Address:**	777 Bloomfield Avenue Glen Ridge, NJ 070282325
Referring Provider:	Dr. Konstantin Walmsley MD	**Location Phone:**	(973) 429-0462

Chief Complaint

IME

History Of Present Illness

Had a vaginal hysterectomy in ~ 2009.
G4P2A2, aged 38 and 26.
She then developed SUI, 1 ppd damp.
Underwent sling in 2010, worked for about 1 year.
Then she started developing worsening incontinence.
Also developed dyspareunia about 6 months after.
This also worsened over time . She felt like was "hitting a hard spot".
Her incontinence is now primarily UUI 3-4 thick pads/day, wet
Also suffers with recurrent UTIs.
Stream is variable.
Takes about 3 Norco/day for back and neck pain.

Past Medical History

Disease Name	Date Onset	Notes
Anxiety	--	--
Bed wetting	--	--
Bladder infection	--	--
Blood in urine	--	--
Coronary artery disease	--	--
DDD (degenerative disc disease), cervical	--	--
Depression	--	--
Hypertension	--	--
Incontinence	--	--
Kidney infection	--	--
Kidney stones	--	--
Osteoporosis	--	--

Past Surgical History

Procedure Name	Date	Notes
Cyst	ovary	--
Excision, vaginal mesh, vaginal approach	--	--
Hysterectomy	--	--

Medication List

Name	Date Started	Instructions
baclofen oral		--
Celexa oral		--
Klonopin oral		--
lisinopril oral		--
Norco oral		--

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Allergy List

Allergen Name	Date	Reaction	Notes
No known drug allergy	--	--	--

Review of Systems

Constitutional
- **Denies** : fever, chills

Eyes
- **Denies** : changes in vision, double vision

HENT
- **Denies** : sore throat, headaches

Cardiovascular
- **Denies** : chest pain, irregular heart beats, dyspnea on exertion

Respiratory
- **Denies** : shortness of breath, sleep apnea

Gastrointestinal
- **Denies** : nausea, vomiting

Genitourinary
- **Denies** : additional symptoms, except as noted in HPI

Integument
- **Denies** : rash, itching

Neurologic
- **Denies** : tingling or numbness, seizures

Musculoskeletal
- **Denies** : back pain, muscular weakness

Endocrine
- **Denies** : cold intolerance, heat intolerance, weight gain, weight loss

Psychiatric
- **Denies** : anxiety, depression

Heme-Lymph
- **Denies** : easy bleeding, lymph node enlargement or tenderness

Allergic-Immunologic
- **Denies** : frequent illnesses

Vitals

Date	Time	BP	Position	Site	L\R	Cuff Size	HR	RR	TEMP(°F)	WT	HT	BMI kg/m^2	BSA m^2	O2 Sat	HC
01/12/2017	03:21 PM									180lbs 0oz	5' 2"	32.92	1.89		

Physical Examination

Constitutional
- **Appearance** : Well nourished, well developed patient in no acute distress. Ambulating without difficulty.
- **Ability to Communicate** : Normal communication ability

Eyes
- **Conjunctiva and Eyelids** : Conjunctiva and eyelids appear normal
- **Sclera** : White without injection

Neck
- **Thyroid** : gland size normal, nontender, no nodules or masses present on palpation, gland position midline, trachea midline

Chest
- **Respiratory Effort** : breathing unlabored, no accessory muscle use
- **Auscultation** : normal breath sounds

Cardiovascular
- **Heart** :
  - **Auscultation** : Heart rate is regular with normal rhythm. No murmurs are heard.
- **Peripheral Vascular System** :

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- **Peripheral Circulation** : No evidence of edema, cyanosis or distal hair loss present. No purpura present. Normal capillary refill. No varicosities are present.

Gastrointestinal

- **Abdominal Exam** : tone normal without rigidity or guarding, no CVA or abdominal tenderness, normal bowel sounds, no masses present, non-distended
- **Hernias** : No evidence of a right inguinal hernia, No evidence of a left inguinal hernia, no incisional hernias present, normal appearing umbilicus

Genitourinary

- **External Genitalia** : normal appearance for age
- **Vagina** : atrophy present, color normal; sling palpable in the area of the mid-urethra, non tender. Mildly indurated tissue noted in the area of the sling.
- **Urethra** :
  - **Urethral Meatus** : Meatus is within normal limits
  - **Urethral Body** : urethra palpation normal, urethra structural support normal, no hypermobility present, no leakage present
- **Bladder** : non-tender to palpation, no masses present, no cystocele present, no rectocele present, no bladder distension present
- **Cervix** : appearance healthy, no lesions present, nontender to palpation, no discharges, no bleeding present
- **Uterus** : Non-tender to palpation without masses. Contour is smooth to palpation with the position in the midline/midplane. Size and shape is normal.
- **Perineum** : perineum normal, perineum intact, no perineal rashes or skin lesions present

Lymphatic

- **Neck** : no neck lymphadenopathy present
- **Groin** : no groin lymphadenopathy present

Musculoskeletal

- **Right Lower Extremity** : no tenderness to palpation, no edema present, no ecchymosis present
- **Left Lower Extremity** : no tenderness to palpation, no edema present, no ecchymosis present

Neurologic and Psychiatric

- **Orientation** : oriented to person, place and time
- **Mood and Affect** : normal, appropriate

Assessment

- Mixed incontinence, urge and stress (male) (female) 788.33/N39.46
- Dyspareunia in female 625.0/N94.10
- Atrophy of vagina 627.3/N95.2
- Back pain 724.5/M54.9

Electronically Signed by: Konstantin Walmsley, MD -Author on January 17, 2017 12:12:48 AM

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